

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: June 15, 2012

1. Company and Correspondent making the submission:

- Submitter's Name : OSSTEM Implant Co., Ltd.
- Address : #507-8 Geoje3-Dong Yeonje-Gu
Busan, 611-804, Republic of Korea
- Contact : Mr. Hee Kwon Son
- Phone: +82 51 850 2575

- Correspondent's Name: HIOSSEN Inc.
- Address: 85 Ben Fairless Dr. Fairless Hills, PA 19030
- Contact: Patrick Lim
- Phone: 888 678 0001

2. Device :

- Trade or (Proprietary) Name : TS Fixture System
- Common or usual name : Dental Implant
- Classification Name : Endosseous Dental Implant.
21CFR872.3640
Class II
DZE

3. Predicate Device:

The HGII Fixture System, HIOSSEN Inc., Ltd, K090237
 The ETIII SA Fixture System, HIOSSEN Inc., K101096
 The GSIII System, Osstem Implant Co., Ltd, K091208
 The ETIII SA Ultra wide Fixture, HIOSSEN Inc., K103537

4. Description:

The TS Fixture System is a dental implant made of titanium metal intended to be surgically placed in the bone of the upper or lower jaw arches.

Fixture is available in various lengths 7.0 to 15.0mm and diameters 3.5 to 6.8mm (TSII SA Fixture : 3.5, 4.2, 4.4, 4.9 / TSIII SA Fixture: 3.75, 3.77, 4.2, 4.25, 4.6, 4.63, 4.65, 5.05,





5.08, 5.1 / TSIII SA Ultra-Wide Fixture : 5.92, 5.95, 6, 6.8) according to the anatomical situation.

Fixture is made of pure titanium metal and supplied sterile. The surface is SA, Sandblasting and Acid etching, treated.

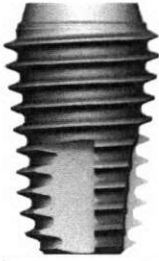

The TS Fixture System is similar to other commercially available products based on the intended use, the technology used, the claims, the material composition employed and performance characteristics.

The TS Fixture System is substantially equivalent in design, function and intended use to the HGII Fixture System of HIOSSEN Inc. (K090237), the ETIII SA Fixture System of HIOSSEN Inc.(K101096), The GSIII System of Osstem Implant Co., Ltd(K091208) and The ETIII SA Ultra wide Fixture of HIOSSEN Inc.(K103537)

- Substantial Equivalence Matrix

	TS Fixture System	Predicate devices		
		HGII Fixture System	GSIII System	ETIII SA Fixture System
Design				
510(K) No.	New Device	K090237	K091208	K101096
Intended use	The TS Fixture System is designed for dental implant surgery; it is placed on the maxillary or mandibular alveolar bone through a surgical procedure, and after osseointegration with the alveolar bone, it can replace a lost tooth by connecting the abutment post. The TS Fixture System is indicated for use in partially or fully edentulous mandibles and maxillae, in support	The HG II Fixture System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support	The GS III System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support	ETIII SA Fixture System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including ; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment

	of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading.	for fixed bridgework. The HG II Fixture System is for single and two stage surgical procedures. It is not for immediate load.	for fixed bridgework. The GS III System is for single and two stage surgical procedures. It is not for immediate load.	support for fixed bridgework. The ET III SA Fixture System is for single and two stage surgical procedures. It is not for immediate load. The Ultra wide Fixture System is intended to be used in the molar region.
Surgery type	One or two stage Surgery	One or two stage Surgery	One or two stage Surgery	One or two stage Surgery
Structure	<ul style="list-style-type: none"> - Internal Hex-connected - Submerged Fixture - Tapered body shape and straight body shape - 4 sided cutting edge with self-tapping 	<ul style="list-style-type: none"> - Internal Hex-connected - Submerged Fixture - Straight body shape - 4 sided cutting edge with self-tapping 	<ul style="list-style-type: none"> - Internal Hex-connected - Submerged Fixture - Tapered body shape and - 4 sided cutting edge with self-tapping 	<ul style="list-style-type: none"> - Submerged Fixture - Self tapping - Internal Hexagonal connection - Taper Body
Body Diameter (D)	TSII SA Fixture: 3.5, 4.2, 4.4, 4.9 TSIII SA Fixture: 3.75, 3.77, 4.2, 4.25, 4.6, 4.63, 4.65, 5.05, 5.08, 5.1	3.5~4.85	3.7~5.1	3.75~5.05
Length (mm)	7.0~15	7.2~15.2	7.0~15.0	7.2~15.2
Material of Fixture	Pure Titanium Grade 4 (ASTM F67)	Pure Titanium Grade 4 (ASTM F67)	Pure Titanium Grade 4 (ASTM F67)	Pure Titanium Grade 4 (ASTM F67)
Surface	SA	RBM	RBM	SA
Sterilization	Radiation Sterile	Radiation Sterile	Radiation Sterile	Radiation Sterile
Shelf life	8years	5 years	5 years	5 years
S. E.	The TS Fixture System has the same material, indication for use and similar design as the HGII Fixture System (K090237) and GSIII System (K091208) except surface treatment. but the surface treatment of TS Fixture System is the same with surface treatment of ETIII SA Fixture System (K101096)			

	TSIII SA Ultra-Wide Fixture	Predicate devices
		ETIII SA Ultra wide Fixture
Design		
510(K) No.	New Device	K103537
Intended use	The TSIII SA Ultra-Wide Fixture is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading.	The ETIII SA Ultra wide System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including ; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework.
Surgery type	One or two stage Surgery	One or two stage Surgery
Structure	<ul style="list-style-type: none"> - Internal Hex-connected - Submerged Fixture - Tapered body shape and straight body shape - 4 sided cutting edge with self-tapping 	<ul style="list-style-type: none"> - Internal Hex-connected - Submerged Fixture - Tapered body shape and straight body shape - 4 sided cutting edge with self-tapping
Body Diameter (D)	5.92, 5.95, 6, 6.8	5.9~6.82
Length (mm)	7.0~12.5	7.2~12.7
Material of Fixture	Pure Titanium Grade 4 (ASTM F67)	Pure Titanium Grade 4 (ASTM F67)
Surface	SA (Sandblasting and Acid etching)	SA (Sandblasting and Acid etching)
Sterilizati on	Radiation Sterile	Radiation Sterile
Shelf life	8years	5years
S E	The TSIII SA Ultra-Wide Fixture has the same material, surface treatment, indication for use and similar design as the ETIII SA Ultra wide Fixture (K103537)	

5. Indication for use :

The TS Fixture System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading.

TS Fixture System is compatible with abutment in the ET/SS Implant System

6. Review :

The TS Fixture System has same material and indication for use and similar design and technological characteristics as the predicate device.

The TS Fixture System has been subjected to safety, performance, and product validations prior to release. Safety tests including biocompatibility have been performed to ensure the devices comply with the applicable International and US regulations.

7. Summary of nonclinical testing

Fatigue testing was considered according to the "Guidance for industry and FDA staff Class II Special Controls Guidance Document Root-form Endosseous Dental Implants and Endosseous Dental Abutment" with the worst case scenario of the GSIII Fixture/ the HGII Fixture and an angled abutment in support of the TSIII SA Fixture and TSII SA Fixture. TS Fixture System has same material and similar design as the GSIII Fixture and the HGII Fixture. Therefore, submitted fatigue test result can be used as a proof of TS Fixture system

8. Summary of clinical testing

No clinical studies are submitted

9. Conclusions

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification Osstem Implant Co., Ltd. concludes that the TS Fixture System is substantially equivalent to the predicate devices as described herein



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 29, 2012

Osstem Implant Company, Limited
C/O Mr. Patrick Lim
Hiossen, Incorporated
85 Ben Fairless Drive
Fairless Hills, Pennsylvania 19030

Re: K121995
Trade/Device Name: TS Fixture System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: November 9, 2012
Received: November 23, 2012

Dear Mr. Lim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Kwame O. Ulmer

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



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510(k) Number K 121995

Device Name : TS Fixture System

Indication for use : The TS Fixture System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading.

TS Fixture System is compatible with abutment in the ET/SS Implant System

Prescription Use X
(Per 21CFR801 Subpart D)

OR Over-The-Counter Use _____
(Per 21CFR807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner DDS, MA 2012.11.29
12:46:27 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: _____